TECHNIQUES AND INSTRUMENTATION

Neovagina creation in vaginal agenesis: development of a new laparoscopic Vecchietti-based procedure and optimized instruments in a prospective comparative interventional study in 101 patients

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Objective: To improve the laparoscopic Vecchietti procedure and optimize instrumentation for treatment of congenital vaginal agenesis with a minimum of complications and optimal functional outcome, in comparison with the conventional laparoscopic Vecchietti procedure.
Design: Prospective comparative interventional study.
Setting: University hospital.
Patient(s): One hundred one patients with congenital vaginal agenesis.
Intervention(s): The interventions compared were [1] a new laparoscopic, Vecchietti-based method using vaginoabdominal blunt perforation without vesicorectal tunneling and [2] the laparoscopic Vecchietti procedure.
Main Outcome Measure(s): Duration of surgery and traction, functional results, surgical and technical complications.
Result(s): Without tunneling and with new instruments, mean operative time was more than halved, from 113.0 to 47.5 minutes, with a significantly reduced complication rate for bladder lesions and no bowel lesions. Mean traction time was similarly reduced, from 11.7 to 4.8 days. No instrument-related complications were seen with our new instrument set. After 6 months, the longer neovagina of 10.6 cm that was achieved with the new method was still 2.5 cm longer than the conventional result. No patients needed lubricants or had sustained pain during intercourse.
Conclusion(s): Our new method for neovagina creation resulted in shorter operation and traction times, better functional results, and fewer surgical complications and no technical ones. It is therefore a safer, shorter, more effective, and less traumatic procedure. (Fertil Steril® 2007;■:■–■. ©2007 by American Society for Reproductive Medicine.)

Key Words: Laparoscopic creation of neovagina, Vecchietti procedure, vaginal aplasia, vaginal agenesis, traction device, Mayer-Rokitansky-Küster-Hauser syndrome, androgen insensitivity syndrome

Vecchietti developed a method (1, 2) for creation of a neovagina in patients with congenital vaginal agenesis by internal stretching of the vaginal dimple after surgical abdominovaginal dissection of the vesicorectal space. This method came into widespread use (3–6) but was associated with the surgical trauma of laparotomy.

Received May 10, 2007; revised and accepted July 10, 2007.
Supported by the German Ministry of Education and Research (BMBF; Berlin, Germany), grant 16SV 1352 ("Minimally invasive technology and therapeutic methods"). The traction device and the newly developed instruments were provided free of charge for the present study by Karl Storz GmbH (Tuttlingen, Germany). The company provided no funding.
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To avoid this, we established the endoscopic approach in 1992 at the Department of Obstetrics and Gynaecology at Heidelberg University Hospital (Heidelberg, Germany) (7, 8) and started a prospective interventional study in three phases to further optimize the procedure and compare the results.

The first phase of the study consisted of standardizing the Heidelberg-Tübingen laparoscopic approach (laparoscopic Vecchietti procedure) with surgical vesicorectal tunneling (i.e., abdominovaginal retrovesical incision of the peritoneum) using conventional instruments. However, this standard approach (9–18), until recently, still involved time-consuming abdominovaginal dissection or tunneling of the vesicorectal space, which caused considerable surgical trauma as a result of extensive dissection and coagulation, associated with the risk of organ damage in the neighborhood of

the surgically created tunnel and the risk of hematoma, fistula formation, scar formation with stenosis, dehiscence of the neovagina, and destruction of the autonomic visceral nerve network. This complex procedure was performed under the assumption that traction threads could thus safely be introduced into the abdomen as the principal step in the Vecchietti method.

The second phase addressed the question of whether the procedure could be optimized by using our new approach that is based solely on blunt vaginoabdominal perforation, thus dispensing with the complex and traumatic surgical tunneling step. This was expected to markedly reduce operation time, but it was unclear whether lesions to the bladder, ureter, and rectum (10) could successfully be avoided, making the procedure safer.

However, this method still was associated with long periods of traction after surgery of a mean of 1 week (8), even of $\leq$2 weeks (14) in some cases, and with technical problems with the Vecchietti instruments (19), such as slippage of the traction device, snapping of the traction threads that necessitated further surgery to reintroduce the threads, or lesions on the surface of the abdomen and displacement of the olive.

The third phase, therefore, aimed to improve the procedure further by using our newly developed set of instruments (20).

The aims of our study were to develop a safer, shorter, more efficient, and less traumatic procedure, also in the presence of renal malformations (21, 22); to modify the instruments to avoid the technical complications; and to optimize the functional outcome.

MATERIALS AND METHODS

Patients and Study Design

The study was a three-phase prospective comparative interventional study in 101 women with congenital vaginal agenesis. The first group of patients underwent the Heidelberg-Tübingen laparoscopic Vecchietti procedure with vesicorectal tunneling (Group 1). The second group underwent the new procedure, involving only blunt vaginoabdominal perforation without vesicorectal tunneling (Group 2). In the third group, we performed the new procedure using the newly designed instruments (Group 3). The groups were not balanced for size.

Our aim was to compare the two laparoscopic Vecchietti-based techniques and the two sets of instruments, that is, the conventional instruments (Fig. 1A, B) and our newly developed set (Fig. 1C, D).

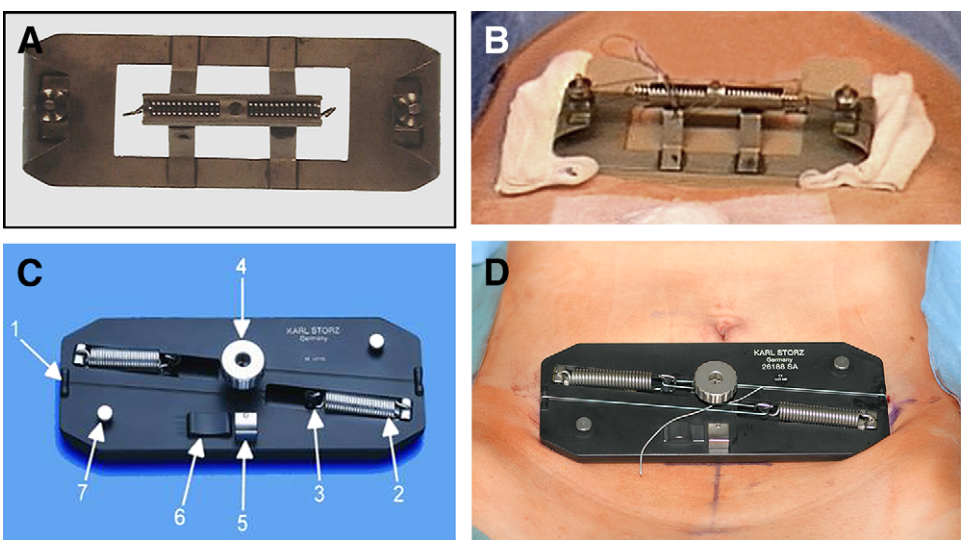
The study was approved by the Ethics Committee of the Medical Faculty of Tübingen University.

Inclusion and Exclusion Criteria

Included were women with congenital vaginal agenesis (as diagnosed clinically or laparoscopically) who were

FIGURE 1

The old (**A**) and new (**C**) traction devices, their positioning (**B**, **D**), and the securing of the traction threads under tension. (**C**) Numbering indicates the following: 1 and 3 = movable rollers to prevent the traction threads from snapping; 2 = tension spring set at optimum traction; 4 = single traction ratchet for even, stepwise tension via both threads to avoid dehiscence and tearing of the neovagina; 5 = lever to release tension for short periods; 6 = safety lever to fix the traction ratchet and prevent inadvertent release by the patient or attending physician; and 7 = pan-head screw for easy disassembly for autoclaving.



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a minimum of 14 years of age, had the wish to undergo creation of a neovagina, were emotionally mature, and had adequate motivation for prolonged follow-up treatment (use of an indwelling dummy for several months).

Excluded were women with multiple previous laparotomies or with vaginal atresia after pelvic exenteration for cancer and women who were sexually immature. The presence of renal deformities (e.g., single pelvic kidney) was not an exclusion criterion.

Assessments

Before treatment, all patients underwent a full clinical examination, karyotyping, sonography, and either intravenous pyelography or magnetic resonance imaging of the kidneys and urinary tract. Most of the patients had undergone previous diagnostic laparoscopy.

Instruments

Laparoscopic creation of a neovagina was based on the principle of the Vecchietti method, with stretching of the vaginal dimple via controlled traction on a mold that was pulled by subperitoneal threads which emerged on the abdominal surface and were attached to a traction device.

This technique requires special instruments, including a traction device, thread guides, and applicators.

Traction device A new traction device was developed to avoid complications that were seen with the conventional device, such as lesions to the surface of the abdomen, slippage of the traction device, snapping of the traction threads, and dehiscence of the vagina as a result of uneven traction. The new traction device was therefore redesigned (Fig. 1C): all edges were rounded, and only flat, smooth surfaces came into contact with the skin, obviating the need for cushioning materials. Movable rollers also were integrated to prevent the traction threads from snapping. A single traction ratchet was designed to apply even, stepwise tension via both threads to ensure that the segmented dummy was pulled in only one direction, to avoid dehiscence and tearing of the neovagina. The mechanical improvements to the traction device ensured that the neovagina did not tear, thanks to even pressure from the freely adjustable tension roller.

Thread guides We redesigned Vecchietti's original straight thread guide and developed curved thread guides with a greater curvature to enable the traction device to be positioned as near as possible to the lower edge of the navel, to establish whether this optimized its anatomical position, avoided displacement of the olive toward the bladder, and resulted in better neovagina lengths.

Vaginal dummies We made some small modifications to the available segmented dummy used for traction (19, 23). Our optimized model matches the shape of the dummies used after surgery. It has five linked segments and a diameter of 2.5 cm, and it is 10 cm long, which means that the degree of penetration or the actual length of the neovagina can be assessed easily during the traction period, and it has a central bore to enable secretions to flow freely.

For all operations, we inserted all five linked segments at once and did not add each segment individually. This was to establish whether the segmented dummy avoided complications seen with the olive (e.g., displacement toward the bladder or the potential narrowing of the part of the neovagina that the olive has already passed [24]) and affected the width of the neovagina. The postoperative vaginal dummies necessary to maintain the achieved result have a completely sealed surface and are available in six sizes (10- and 12-cm lengths with diameters of 2, 2.5, and 3 cm). All dummies are made of biocompatible and autoclavable material.

Surgical Techniques

Details of, and differences between, the two surgical methods are described in this subsection.

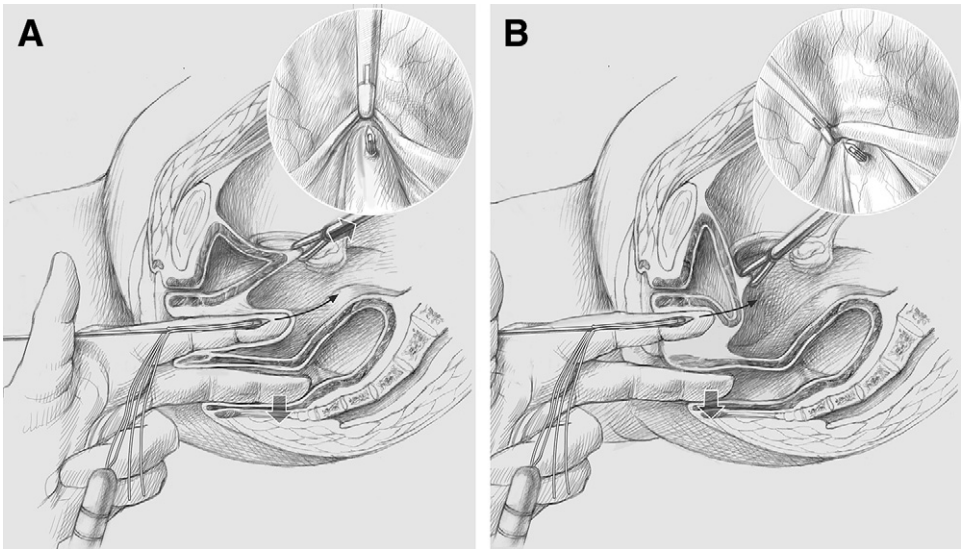
Procedure with surgical vesicorectal tunneling: the Heidelberg-Tübingen Vecchietti procedure by laparoscopy (Group 1) Three endoscopically introduced suprapubic trocars are required for tunneling (7). The Douglas pouch was opened, and the vesicorectal space was dissected to form a tunnel between the bladder and rectum. The traction threads then were drawn into the abdominal cavity through the vaginal dimple and the prepared tunnel by using a straight thread guide under endoscopic control. After the curved thread guide was inserted and advanced retroperitoneally to the peritoneal incision to pull the threads through the peritoneum abdominally, the peritoneum was closed with several simple interrupted sutures.

New laparoscopic procedure without vesicorectal tunneling (Groups 2 and 3) Our laparoscopic procedure requires only a single suprapubic trocar. First, the direction of the perforation to introduce the traction threads into the abdominal cavity through the vaginal dimple was diaphanoscopically checked by using simultaneous laparoscopy and cystoscopy in image-in-image mode. The later cranial pole of the vagina needed to lie dorsally on the connecting fibrous band of the rudimentary uterus. The vaginal dimple was then pushed abdominally with controlled digital pressure from the left forefinger, until it almost perforated the vaginal dimple. At the same time, the straight thread guide, with the two threads (Terylene 3+4, Serag–Wiessner KG, Naila, Germany) attached to the dummy, was inserted under this finger and followed the path of the finger to the proximal end of the dimple. Also at the same time, the rectum was distanced dorsally with the left middle finger (Fig. 2A). During this step, it is essential that the band of the rudimentary uterus is drawn ventrally and cranially upward with laparoscopic forceps, to ensure that the bladder is not lying over the point of perforation and cannot be punctured. Figure 2B shows the incorrect position.

The vaginal dimple was then perforated without previous surgical laparoscopic tunneling of the vesicorectal space.

FIGURE 2

Correct (**A**) and incorrect (**B**) positions during perforation of the vaginal dimple.



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The threads were laparoscopically detached from the thread guide, and the thread guide was retracted. Lesions of the bladder and rectum were excluded by cystoscopy and rectal palpation. With a half-filled bladder, the curved thread guide was inserted at the marked points on the abdominal surface and advanced retroperitoneally, down to the upper pole of the vagina (Fig. 3). Each thread was threaded into the guide and drawn back subperitoneally through the abdominal wall (Fig. 4). A suprapubic catheter was inserted under cystoscopic control because the transurethral catheter has to be removed to avoid necrosis of the urethra caused by pressure from the dummy. The suprapubic catheter was left in place until the traction device was removed.

The traction was applied as cranioventrally as possible, with the cranial edge of the device below the lower curve of the navel, allowing the greatest potential for maximizing the length of the neovagina. In contrast to the conventional Vecchietti positioning in the suprapubic region, our positioning prevents the creation of a neovagina that is too short and also avoids bladder lesions that are caused by displacement of the segmented dummy if the traction is applied too ventrally, as has been reported elsewhere (14, 19).

Postoperatively, pain during daily tightening of the traction threads was managed via an epidural catheter.

Follow-Up

Once the 10-cm segmented dummy had been drawn into the vagina completely, the dummy and the traction device were removed. The postoperative functional length of the neovagina was then determined, and the postoperative dummy was inserted immediately to prevent adhesions in the neovagina. Patients were offered analgesic sedation or brief mask anesthesia.

The size of the vaginal dummy depended on patient comfort and functional considerations and was chosen so that the lower end of the dummy was flush with the vaginal introitus or the labia minora. Patients were instructed to wear the vaginal dummy continuously for several months after surgery, always with a liberal coating of estrogen-containing cream, and to clean it in the first few weeks with disinfectant and then with standard soap. As soon as patients were comfortable with the use of the dummy, they were discharged home.

In the first 3 postoperative months, the vaginal dummy should be removed only to urinate or defecate, to take a bath, or to allow sexual intercourse; the latter is not advised until about 3 weeks after surgery. Wearing the dummy at night for a further 3 months is then recommended, although this depends on the frequency of sexual intercourse, the length and width of the neovagina, and the degree of epithelialization. If the patient is not having regular sexual intercourse after epithelialization, the vaginal dummy should be worn at night, two or three times per week, for a few more months, because there is a risk of secondary shrinkage of the neovagina without regular sexual intercourse (18).

Study Variables and Statistical Analysis

The following study variables were determined and statistically analyzed:

Demographics: age, diagnosis, renal malformations, skeletal malformations, preoperative depth of vaginal dimple, and predistension;

FIGURE 3

Insertion of the curved thread guide, down to the upper pole of the vagina.

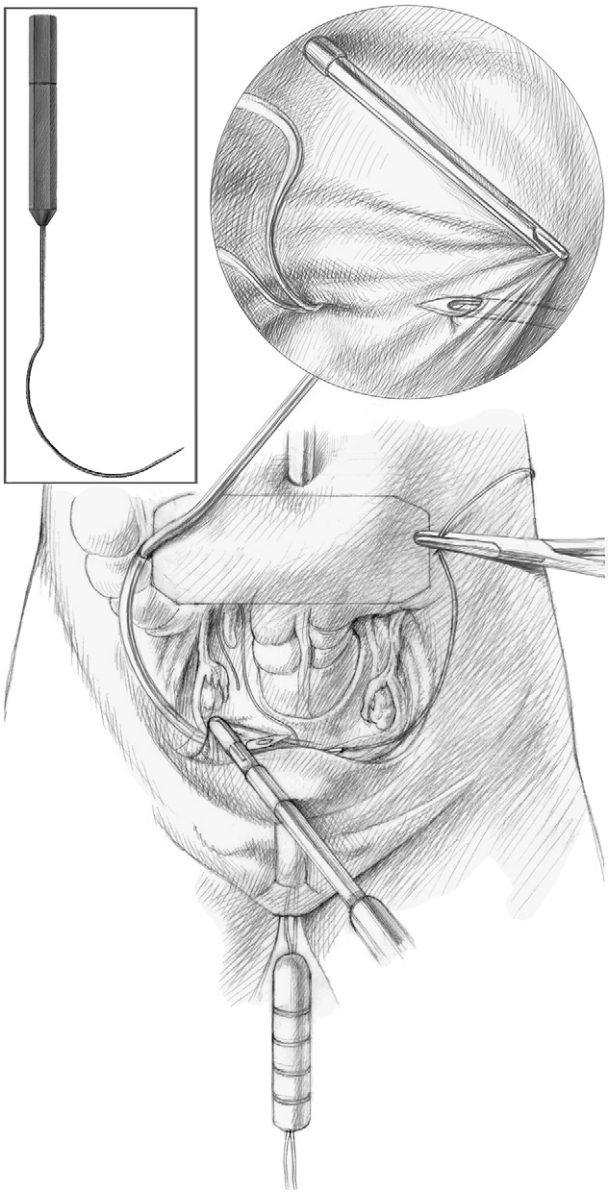

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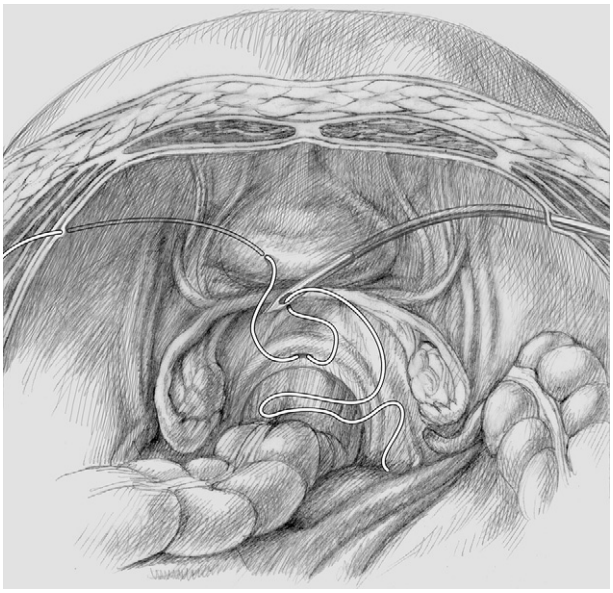
FIGURE 4

Drawing of threads subperitoneally through the abdominal wall.



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Method-related outcomes: durations of surgery, traction, and hospital stay;

Functional outcomes: anatomical (resting state) and functional (on extension) lengths at 0, 3, and 6 months and at last follow-up examination; width of neovagina; and time to complete epithelialization;

Complications: intraoperative organ damage and bleeding, postoperative fever, urinary tract infection, hematuria, hematoma and urethral necrosis, instruments (thread snapping, traction device, slippage, abdominal skin lesions, displacement of dummy), and any complications during follow-up (analgesic use, tissue granulation, adhesions, bleeding, problems with urination or defecation);

Follow-up duration: and

Sexual activity after surgery: number of sexually active patients, time to starting sexual intercourse, pain on intercourse, and need for lubricant.

We used SAS software (version 9.1.3 for Windows; SAS Institute Inc., Cary, NC) for the statistical analyses. The comparisons between the groups were made by using the Student's *t*-test at the 5% significance level. Because only the means and minimum and maximum values for the patients who were treated with conventional instruments with tunneling (Group 1) were available, the SDs for these variables were first of all calculated on the basis of the ranges (25).

RESULTS

Patients, Underlying Disease, Type of Surgery, and Instrumentation

The study enrolled 101 patients, 93 (92.0%) with Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome and 8 (7.9%) with androgen insensitivity syndrome. The first 11 patients were treated in Heidelberg between 1992 and 1998, and the remaining 90 patients, in Tübingen between 1999 and 2006. Each of these series of patients was treated by the same surgical team. The first 12 patients (Group 1) were

treated by the Heidelberg-Tübingen laparoscopic Vecchietti approach, using the conventional instrument set. Our newly developed method was used in the subsequent 18 patients (Group 2). The improved instruments with the newly developed approach were used in the last 71 patients (Group 3).

Table 1 shows demographic details and the preoperative status by treatment group. There were no differences between the mean ages of patients in the different groups. In patients with MRKH syndrome, deformities of the urinary tract were present in similar proportions of patients (Groups 2 and 3 only). However, there were significant differences ($P<.05$) between the groups as regards predistension. About two thirds (61.1%) of the patients in Group 2 (conventional instruments without tunneling) but only 16.9% in Group 3 (optimized instruments without tunneling) performed predistension before surgery. As a result of the predistension, the mean preoperative vaginal dimple length also significantly differed between these groups ($P=.0132$), but with the shorter preoperative length in Group 3, which had a significantly ($P<.0001$) longer postoperative length (Table 2), along with a significantly ($P=.0001$) shorter duration of traction. Therefore, there was no significant correlation ($P>.05$) between duration of traction and performance of predistension or not (Fig. 5A) and also no correlation ($r = -0.097$) between traction duration and preoperative length in these groups (Fig. 5B).

Method-Related Outcomes

The procedure was completed successfully in all patients. The efficiency of the operation in terms of duration was markedly improved by not performing surgical vesicorectal tunneling, yet this did not result in a higher rate of lesions to the bladder or rectum. Despite not performing vesicorectal tunneling, we were able to more than halve the duration of traction and achieve a mean neovagina length that was longer than with tunneling (Table 2).

Without tunneling, the mean duration of surgery in Group 2 (93.5 min) was much shorter than in Group 1, which had surgical vesicorectal tunneling (113.0 min). The use of the optimized instruments, combined with our new method without tunneling (Group 3), resulted in a further significant reduction, to a mean of 47.5 minutes ($P<.0001$). The duration of surgery therefore was more than halved by not dissecting the vesicorectal space and using the optimized instruments.

This did not lead to a higher rate of intraoperative complications, however. None of the patients developed rectal lesions. Accidental perforation of the bladder by the thread-bearing needle occurred in 1 (8.3%) of 12 patients with tunneling and in 3 (3.4%) of 89 without tunneling (2 [2.8%] of 71 patients when using the optimized instruments and 1 [5.6%] of 18 when using the conventional instruments). This was able to be corrected immediately without surgical repair and sequelae.

TABLE 1

Demographic data and preoperative status, by treatment group, of the 101 vaginal agenesis patients who underwent neovagina creation in this study.

Variable	Group 1: with tunneling and using conventional instruments (n = 12)	Group 2: without tunneling, but using conventional instruments (n = 18)	Group 3: without tunneling, and using optimized instruments (n = 71)
Age (y)	19.2 ± 6.1	20.1 ± 5.2	21.5 ± 6.4
Diagnosis, n (%)			
MRKH	10 (87.5)	17 (94.4)	66 (93.0)
AIS	2 (12.5)	1 (5.6)	5 (7.0)
Deformities,[a] n (%)			
Urinary tract [pelvic kidney]	NR	5 (27.8) [1 (5.6)]	17 (25.8) [5 (7.0)]
Skeletal[b]	NR	3 (17.6)	5 (7.6%)
Preoperative depth of vaginal dimple (cm)	NR	2.6 ± 1.6	1.5 ± 1.4
Predistension, n (%)			
Yes	NR	11 (61.1)	12 (16.9)
No	NR	7 (38.9)	59 (83.1)

Note: All values are mean ± SD, unless otherwise indicated. NR = not recorded; AIS = androgen insensitivity syndrome.

[a] MRKH patients only.

[b] As follows in Group 2: hip dysplasia (1 patient), spondylolisthesis (1), and jaw deformity (1). As follows in Group 3: multiple deformity syndrome (2 patients), hip dysplasia and deformity of thumb (1), Klippel-Feil syndrome (1), and hip dysplasia (1).

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TABLE 2

Comparison of functional outcomes (mean ± SD) in patients treated with or without surgical tunneling, using conventional or optimized instruments.

Variable	Group 1: with tunneling, and using conventional instruments (n = 12)	Group 2: without tunneling, but using conventional instruments (n = 18)	Group 3: without tunneling, and using optimized instruments (n = 71)	Groups 2+3: without tunneling, using all instruments (n = 89)
Postoperative length[a] (cm)	8.9 ± 2.0	7.8 ± 1.6	9.6 ± 1.3[b]	9.3 ± 1.5
Postoperative width (finger's width)	2.0 ± 0.0	2.0 ± 0.0	2.0 ± 0.1	2.0 ± 0.0

[a] Intergroup differences were calculated for Groups 2 plus 3 vs. Group 1 and for Group 3 vs. Group 2.
[b] Statistical significance ($P<.05$) was attained only for the difference between Group 3 and Group 2 (*$P<.0001$).

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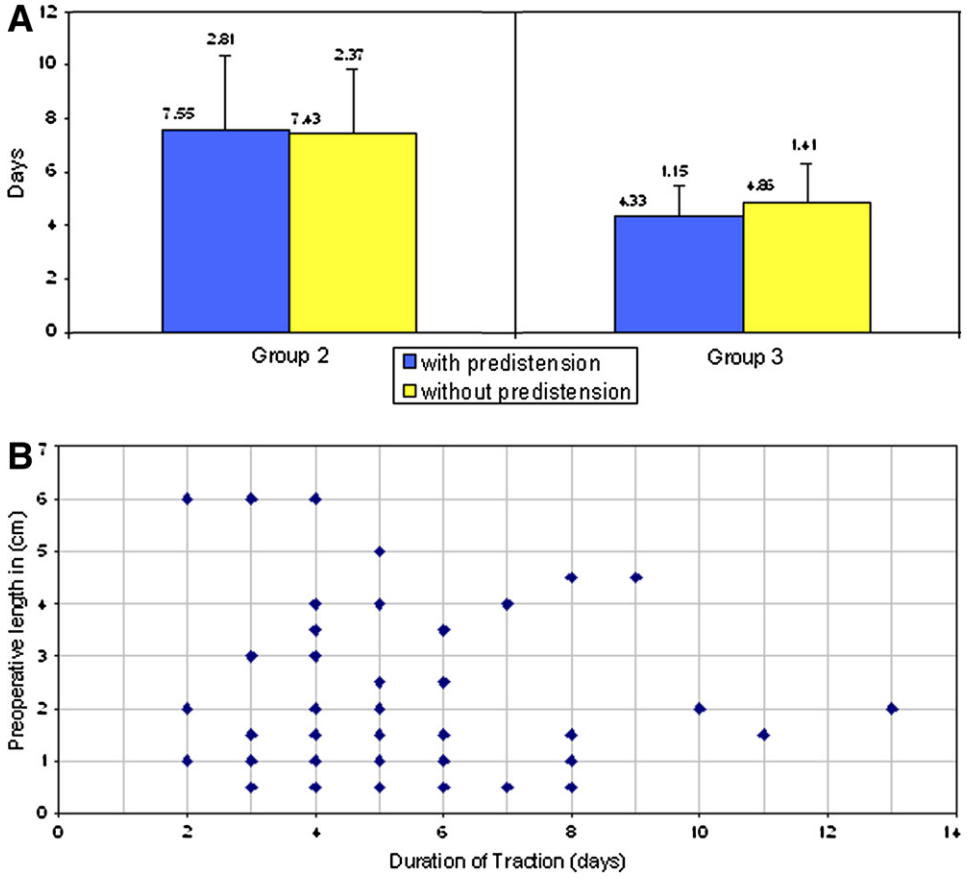
FIGURE 5

(**A**) Relationship between duration of traction and predistension (yes/no) for Group 2 (n = 18) and Group 3 (n = 71). There was no significant correlation ($P>.05$) according to the Student's *t*-test for independent samples. (**B**) Scatterplot of duration of traction vs. preoperative vaginal length for Group 2 (n = 18) and Group 3 (n = 71). There was no significant correlation ($r = -0.097$) according to the Student's *t*-test ($P=.3789$) for independent samples.



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With the new traction device, the mean duration of traction in Group 3 (without tunneling) was 4.8 days. This was significantly shorter than in Group 2 (conventional traction device without tunneling; 7.5 d; $P<.0001$) and was also significantly shorter than the 11.7 days in patients who underwent tunneling (Group 1; $P<.001$). There was no relationship between the preoperative depth of the vaginal dimple and the duration of traction (Fig. 5B).

As would be expected, the significantly shorter duration of traction resulted in a significantly shorter hospital stay (Group 2: 11.8 d; $P=.0105$; Group 3: 8.6 d).

Functional Outcomes

The longest mean postoperative vaginal length of 9.6 cm was achieved in Group 3 without vesicorectal tunneling and using the optimized instruments. It was significantly longer than the 7.8 cm that was achieved by using conventional instruments in Group 2 ($P<.0001$) and was also longer than in Group 1, in which tunneling was performed (8.9 cm; Tables 2 and 3). This longer postoperative length was achieved with the shortest traction time, despite a shorter preoperative dimple depth (Group 2, 2.6 cm vs. Group 3, 1.5 cm) and a much higher incidence of predistension in patients in Group 2 (61.1% vs. Group 3, 16.9%; Fig. 5A and B).

Surgical Complications

Laparoscopic complications (unrelated to vaginal agenesis or the actual Vecchietti procedure but caused by Veress needle injury to a blood vessel at the beginning of laparoscopy) resulted in conversion to laparotomy in one patient, who was nonetheless treated using the new approach, with optimized instruments. The findings in this patient for duration of surgery, duration of hospital stay, and duration of traction were not included in the analysis, because it can be assumed that the laparotomy alone prolonged these.

During the traction period, one patient in Group 1 (8.3%), two patients in Group 2 (11.1%), and seven patients in Group 3 (9.9%) developed postoperative fever. All were treated with IV antibiotics, and the fever subsided uneventfully within 24 hours. One patient in Group 1 (8.3%), two patients in Group 2 (11.1%), and eight patients in Group 3 (11.3%) developed urinary tract infections that responded uneventfully to appropriate treatment. Hematuria was seen in one patient in Group 2 (5.6%) and in two patients in Group 3 (2.8%); and one patient each in Groups 2 (5.6%) and 3 (1.4%) developed hematoma of the bladder, resulting in cystoscopy during removal of the traction device and thorough irrigation of the bladder. Neither of those patients had lesions of the bladder, and there were no further problems. One patient in Group 3 had necrosis of the urethra as a result of late removal of the perioperative transurethral catheter, and a further patient in Group 1 had necrosis in the introital region. Both lesions healed uneventfully within 4 weeks.

Assessments and Complications During Follow-Up

The mean follow-up periods in Groups 2 and 3 were 37.7 and 15.5 months, respectively. Six patients in Group 2 and nine in Group 3 were lost to follow-up after 3 months. After use of the new traction device, the longer functional neovagina length in Group 3 remained significantly longer during follow-up (10.7 cm after 3 mo) than the neovagina length that was achieved by using conventional instruments in Group 2 (8.3 cm after 3 mo, $P<.0008$). This significant difference was maintained at 6 months ($P<.0001$), with almost the same results. A significant difference was no longer present at the last follow-up visit, but the mean length was still longer in the patients treated with the optimized instruments (Table 3). Epithelialization of the vagina was achieved after a mean of 10.1 months (Group 3).

In Group 1, in which tunneling was performed, three patients (25.0%) needed additional dilatation under anesthetic after 4 weeks, whereas in Group 2 (conventional instruments, without tunneling), two patients (11.1%), and in Group 3 (optimized instruments, without tunneling), one patient (1.4%), developed vaginal synechiae that needed surgical correction after the patient failed to wear the vaginal dummy in the first few weeks after surgery. Two of the three patients had normal sexual intercourse in the follow-up period. The third refused follow-up examinations after surgical correction. One patient in Group 2 underwent repeat, laparoscopically assisted creation of a neovagina without vesicorectal tunneling 6 months after the first intervention, because she had not been using the vaginal dummy postoperatively as required and secondary shrinkage had occurred. One year after follow-up surgery, a functional vagina length of 10.0 cm was achieved. Repeated vaginal bleeding occurred in one patient in Group 1 and in one patient in Group 3 and was caused by areas of granulation tissue. Both patients underwent surgery for ablation and coagulation, after 6 and 4.5 months, respectively, and then developed only spotting, which stopped after complete epithelialization was achieved.

Dehiscence of the neovagina occurred in one patient each in Groups 1 and 2. In the first patient, this had to be treated with a surgical suture, and the second patient needed only vaginal application of INTERCEED (absorbable adhesion barrier; Ethicon, Inc., Somerville, NJ) on the defect, both under brief anesthesia.

None of the patients required regular analgesic treatment at home for prolonged periods after surgery, and there also were no problems with urination or defecation during follow-up (except for urinary tract infections). No fistula or postoperative hematoma was seen.

Sexual Activity After Surgery

The mean time to first sexual intercourse was 5.7 months in Group 2 and was 4.3 months in Group 3. In Group 2, 11 of 12 patients asked (6 had been lost to follow-up) had had regular sexual intercourse, and in Group 3, this was true of 33 of

TABLE 3

Comparison of functional outcomes (mean ± SD) in patients treated without surgical tunneling, using conventional or optimized instruments.

Variable	Group 2: conventional instruments (n = 18)	Group 3: optimized instruments (n = 71)
Anatomical length (cm)		
After 3 mo	NR	9.1 ± 1.1
After 6 mo	NR	8.9 ± 1.4
At last follow-up visit	7.4 ± 1.3	8.6 ± 1.2[a] (*P*=.0051)
Functional length (cm)		
After 3 mo	8.3 ± 0.6	10.7 ± 1.1[a] (*P*=.0008)
After 6 mo	8.1 ± 1.2	10.6 ± 1.3[a] (*P*<.0001)
At last follow-up visit	9.6 ± 1.4	10.3 ± 1.2
Anatomical width (finger's width)		
After 3 mo	NR	1.2 ± 0.3
After 6 mo	NR	1.2 ± 0.3
At last follow-up visit	NR	1.2 ± 0.3
Functional width (finger's width)		
After 3 mo	2.0 ± 0.0	1.9 ± 0.2
After 6 mo	2.0 ± 0.0	1.9 ± 0.2
At last follow-up visit	2.0 ± 0.0	1.9 ± 0.2
Time to first sexual intercourse (mo)	5.7 ± 10.1	4.3 ± 4.9
Time to epithelialization (mo)	NR	10.1 ± 6.2
Maximal time of follow-up	37.7 ± 15.5	15.5 ± 9.1

Note: NR = not recorded.

[a] Significant difference in the *t*-test for independent samples.

Brucker. Neovagina creation in vaginal agenesis. Fertil Steril 2007.

50 patients asked (9 had been lost to follow-up, and there were 12 with follow-up of <3 mo). The remaining patient had had satisfactory sexual intercourse from 3 months after surgery after repeat laparoscopically assisted creation of a neovagina. Superficial dyspareunia at the start of coitus was reported by two patients in Group 2 and by five patients in Group 3. In Group 1, all patients had sexual intercourse, because a firm partnership was a precondition for treatment when these patients had surgery; eight had no problems, one patient reported regular dyspareunia, and three required additional dilatation under anesthetic.

None of the patients who reported intercourse needed to use a lubricant.

Technical Complications With Optimized and Conventional Instruments

Traction device No complications were seen with the new traction device. With the conventional device, snapping of traction threads occurred in 6 patients, the device twisted out of position in 10 patients, and 5 patients developed lesions on the abdominal skin.

Other devices There were no complications with the segmented dummy or the thread guides.

DISCUSSION

Without corrective measures, a woman with vaginal agenesis cannot have normal sexual intercourse and may have difficulty sustaining stable relationships. Most commonly, combined agenesis of the uterus, cervix, and upper two thirds of the vagina is associated with the MRKH syndrome but also occurs in androgen insensitivity syndrome. Women with Müllerian agenesis have a normal female phenotype, endocrine status, and external sex characteristics. Hence, it is all the more important that intercourse feels normal to both partners and that the effects of the surgery are not externally visible. This makes a decisive contribution to the patient's integrity as a woman and minimizes the disturbance of her gender identity (26).

The correction of an absent vagina requires the creation of a tunnel between the bladder and rectum (27) by pressure, as in Frank's dilator method (28), dissection, or tunneling to

accommodate the neovagina. Since the advent of the McIndoe and Banister (29) vaginoplasty procedure with vaginal sharp dissection of the vesicorectal space, there has been a trend toward optimized and less traumatic methods of creating a neovagina. Vecchietti's open laparotomy procedure (1), with considerable complications (30) and involving complete abdominovaginal dissection of the vesicorectal space, was improved in the early 1990s by the introduction of laparoscopy (8). After this modification of the Vecchietti procedure by replacing laparotomy with laparoscopy (7), many reports on experience with the laparoscopic method were published. Most, however, were of only small numbers of patients (10–13, 17, 31–39). However, all the investigators continued to adhere to the principal and complex step: the surgical abdominovaginal sharp dissection of the vesicorectal space to create a tunnel for assumedly safe introduction of the threads into the abdomen. Fedele et al. (9) reported in 1994 on two patients treated with the laparoscopic Vecchietti method in whom vesicorectal dissection was dispensed with but abdominovaginal sharp tunneling of the vesicorectal space still was used, followed by blunt perforation.

In 1995, Hucke (10) again recommended complete vesicorectal dissection for the procedure, because introducing of the threads was safer as a result of separation of the bladder and rectum, because the vesicorectal space is very narrow, especially in MRKH patients. That investigator reported one case of misapplication of the traction threads through the bladder, when the dissection had not been deep enough.

Busacca et al. (40) reported on one patient in whom they were able to dispense with dissection of the vesicorectal space by using a combined laparoscopic and ultrasound technique that enabled the needle to be accurately guided from the pseudohymen to the peritoneal cavity. Similarly, Giacalone et al. (41, 42) reported passing the traction sutures through the vesicorectal space under ultrasound guidance by using a modified Vecchietti procedure in seven patients. The same team had reported elsewhere on a technique in three patients (43) whereby a 30-cm-long needle was introduced into the vesicorectal wall by the perineal route, and the two threads were inserted intraabdominally. The progress of the needle between the bladder and the rectum was directed by a finger in the rectum and by concomitant cystoscopy. This method, which was not further pursued for unknown reasons, also dispensed with vesicorectal dissection, with the investigators stating that in addition to other advantages, this avoided postoperative sclerosis, the source of secondary neovaginal stenosis.

Giacalone et al. (41, 42) and Laffargue et al. (43) used traction threads that ran freely through the abdominal cavity. Laffargue et al. (43) emphasized the risk of postoperative intestinal obstruction, and Borruto et al. (44) commented that this increased the potential for neovaginal prolapse because the traction threads did not run entirely subperitoneally.

In 2000 and 2006, respectively, Fedele et al. (16) and Folgueira et al. (45) reported studies in larger numbers of patients. These studies sought to optimize the Vecchietti procedure in terms of dispensing with dissection but still used abdominovaginal retrovesical incision of the peritoneum and subsequent sharp tunneling of the vesicorectal space, followed by blunt abdominovaginal perforation of the vaginal dimple to hook the threads attached to the olive before drawing them back into the abdominal space and subperitoneally up to the traction device. Fedele et al. (16) reported that they further simplified the Vecchietti technique in 38 of 52 patients by passing the thread guide only once, abdominally-vaginally, through the vesicorectal space. Folgueira et al. (45) also performed a modified Vecchietti procedure in 18 patients. They also did not dissect the vesicorectal space, to minimize the risk of hematoma and fistula formation. Like Fedele et al. (16), however, they did perform laparoscopically assisted sharp abdominovaginal tunneling between the bladder and the rectum.

The aim of our study was therefore to optimize the Vecchietti procedure, first by developing a standardized laparoscopic approach with abdominovaginal complete dissection of the vesicorectal space (7); then by optimizing the procedure in terms of dispensing with dissection, tunneling, and the use of additional imaging tools, instead performing only vaginoabdominal blunt perforation of the vaginal dimple for intraabdominal insertion of the threads; and last by using newly developed, technically superior instruments to show that our newly developed method in combination with the new instruments provides a safer, shorter, and more effective minimally invasive method of neovagina creation, compared with the more traumatic laparoscopic Vecchietti procedure.

The present prospective interventional study was the first to compare the conventional laparoscopic surgical and instrumental approach with a new surgical approach and a new and optimized set of instruments in the creation of a neovagina. We showed that dispensing with surgical vesicorectal tunneling and using vaginoabdominal blunt perforation of the vaginal dimple instead was not associated with higher complication rates or poorer functional outcome and was much more efficient. The improved technique and instruments resulted in a low rate of intraoperative and postoperative complications and a shorter duration of surgery. Both improvements resulted from the omission of the tunneling step and the occurrence of a learning curve, which was observed as the actual procedure was standardized and training in the new technique progressed. Because the tunneling procedure used in Group 1 has been standard for many years, it may be assumed that a learning curve no longer exists for that step. The improved technique also more than halved the traction time and achieved better functional results, that is, a longer neovagina. There was no significant correlation between duration of traction and preoperative length of the vaginal dimple with or without predistension. Perforation of the vaginal dimple occurs under laparoscopic and digital control. It is essential that the rudimentary uterus is drawn ventrally and cranially upward during this process with laparoscopic

forceps to avoid bladder injury. We introduced this step after perforating the bladder in three early patients in this study, and we saw no complications of this sort in subsequent patients.

With our new traction device, the mean traction time was approximately half of that with the conventional instruments, despite tunneling not having been performed, and a significantly improved functional outcome also resulted. This significant reduction in traction time also meant that the hospital stay was shorter than with the conventional method. A mean of 8.6 days for the hospital stay is still relatively long, but this is because patients come from all over Germany for treatment, are admitted 1 day before surgery, and remain on the ward until they have fully recovered and because therapy takes a holistic approach, with complete psychological evaluation and counseling.

We saw none of the mechanical complications with the conventional instruments (slippage and twisting of the traction device, snapping of traction threads, abdominal pressure lesions), nor did we observe fistula formation, ileus, vaginal prolapse, or scar formation at long-term follow-up examinations.

Accidental perforation of the bladder with the thread-bearing needle occurred in three of the Fedele et al. patients (16) and in two patients in our Group 3, but neither our patients nor those of Fedele et al. (16) needed surgical repair, nor were there long-term adverse effects. The primary difference between the results concerned the traction time. Fedele et al. (16) achieved a mean vaginal length of 7–8 cm after 8 days' traction. The mean in our patients without surgical vesicorectal tunneling was 9.3 cm after a mean of 5.3 days' traction, regardless of the instruments used, and in our patients treated with optimized instruments, the mean vaginal length was 9.6 cm after a mean of 4.8 days' traction. Follow-up after 6 months showed that neovaginal length in the Fedele et al. (16) patients was 6 cm (2 patients) and >7 cm (remaining patients), whereas the mean functional length in our patients at this time was 10.6 cm.

Also, with the Fedele et al. (16) method, and all other methods described, the traction device is placed on the suprapubic region, and usually an olive is used for distension. In our method, the traction device is placed as cranially as possible directly below the navel, and a segmented dummy with a central bore is used. Whereas the olive can cause narrowing of the distal neovagina and prevent vaginal secretions from flowing freely, the segmented dummy avoids this problem and even allows vaginal douching (13), but it requires the use of a suprapubic catheter in the immediate postoperative period to avoid urethral necrosis. Our segmented dummy also allows maximization of neovaginal functional width during distension, obviating the use of progressively larger dilators in the postoperative period. Unlike our postoperative dummies, the dilators inserted by Fedele et al. (16) after removal of the olive had increasing diameters, from 1.5 to 2.5 cm. The dummy we use is suited to the width that is achieved after distension with the segmented dummy, and the diameter remains the same.

An additional aspect of the functionality of the neovagina is its microscopic similarity to a normal vagina. We demonstrated cytologically that the neovagina became coated with an iodine-positive stratified squamous epithelium. In addition, histology confirmed the formation of periodic acid-Schiff–positive nonkeratinizing stratified squamous epithelium that corresponded to normal vaginal epithelium, confirming findings by Fedele et al. (46). Immunohistochemical reaction with cytokeratin 13 demonstrates normal epithelial cells in squamous differentiations.

This offers a great advantage over techniques that do not use stretching but instead require plastic surgery, as is the case with, for example, the Abbé-McIndoe procedure, in which a split-thickness skin graft covers a mold that is placed into a dissected vaginal space between the rectum and the bladder (29). In contrast to the Vecchietti procedure, the Abbé-McIndoe method is associated with significant skin graft contracture and visible scar formation at the donor site.

The stretching method developed by Frank (28), which involves prolonged use of a vaginal dilator by the patient to apply external pressure to the vaginal dimple, has not gained very wide acceptance for neovagina creation. This is certainly in part due to the fact that the treatment's success depends on the patient's self-discipline and perseverance, her motivation, and the considerable physical and psychological strain the associated pain places on her (47). However, apart from being a lengthy procedure, Frank's method is also associated with a number of medical disadvantages, including vaginal prolapse (48–50), caused by the absence of vaginal supporting structures and scarring (51), and accidental urethral dilatation, resulting in urethral intercourse. None of the above complications have occurred in patients treated by our modern, automated internal traction technique that is based on minimal invasive access, which combines the major advantages of short hospital stay and healing time with excellent functional outcome, resulting in less strain on the patient and greater patient satisfaction.

With regard to our study design, it was, of course, subject to all the possible pitfalls in any surgical clinical study. Even though the treatment groups were homogeneous with regard to background variables, all the usual criticisms leveled against interventional study designs also apply to our study. This applies to almost all surgical clinical studies that compare different surgical methods, and such studies published in the literature on laparoscopically assisted creation of a neovagina are no exception.

For a prospective study, our study took a long time to complete, the main reason being that congenital vaginal agenesis is such a rare disorder.

The method described here did not result in a higher rate of complications than was the case with surgical tunneling of the vesicorectal space. It dispenses with a peritoneal incision and still ensures that the traction threads required for creation of the neovagina run almost entirely subperitoneally. This

shortens the duration of surgery, increases the efficiency of the surgical and postoperative procedures, increases patient comfort, shortens the hospital stay, and has excellent functional results. With minimal trauma and a traction period almost half as long as so far reported, this procedure gives women on whom it is performed a near-normal vagina and should therefore be the method of choice in patients with congenital vaginal agenesis. In Europe, therefore, the method for neovagina creation by surgical traction, as first proposed by Vecchietti in 1965, has come into widespread use (52). In the United States, however, according to Perlman and Hertweck (24), Templeman et al. (26), and the American College of Obstetricians and Gynecologists (53), the most widely used surgical procedure for neovagina creation is still the Abbé-McIndoe operation.

The advantage of the Vecchietti-based methods is that they create a neovagina with a normal anatomy (54), histomorphology, and functionality (46, 55, 56). Moreover, there is no need to use extraneous tissues such as skin, peritoneum, or intestine or to perform plastic surgery that causes visible external scars, and a functional result is achieved very quickly. It also is possible to treat any concurrent endometriosis or uterine anomaly (26) or to remove the gonads in case of androgen insensitivity syndrome during the procedure.

In conclusion, we believe that our method comes closest to the ideal proposed by the American College of Obstetricians and Gynecologists (53), Templeman et al. (26), and Laufer (57), because we were able to show that this low-risk procedure creates a vaginal canal in the correct axis, which is of adequate size and secretory capacity to allow intercourse to take place without the need for continual postoperative dilatation and which therefore requires minimal care to maintain long-term effects. Despite simplification, however, this remains a complex surgical and endoscopic procedure that should be performed centrally at high-volume institutions (57) at which clinicians have the necessary experience with diagnosis, therapy, and psychosocial follow-up, as well as familiarity with possible complications (53). Also, it is important to ensure that the first attempt is successful, because repeat surgery increases the risk of surgical injury to the surrounding tissues and of a poor functional outcome, which may have long-term sequelae for the patient's psychological and sexual health (45, 53).

Acknowledgment: The authors are grateful to the German Ministry of Education and Research (BMBF) for their support of this research.

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